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Attorney Docket: JWB-2001-1-P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Harold Mermelstein et al.
Serial No. : 10/037,526
Filed : January 4, 2002
For : Composition and Method for
Treatment of Vaginal Dryness
Art Unit : 1615
Examiner : Rachel M. Bennett

RESPONSE TO FINAL REJECTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SIR:

Reconsideration is requested of the Office Action (hereinafter "Action" or "Final Rejection") dated February 24, 2004 relating to the above-referenced application. In that Action, claims 1-6, 13-18 and 25-31 have been finally rejected, and claims 7-12 and 19-24 have been withdrawn from consideration. For reasons discussed below, and in the Amendment filed November 18, 2003, applicants submit that the rejection is untenable on legal as well as on factual grounds.

Claims 1-6 and 13-15 have been finally rejected under 35 U.S.C. 103(a) as unpatentable over Newmark and further in view of Gehling et al., Remington's Pharmaceutical Science, all of which are of record, and newly cited Stuart et al. U.S. 20030207971. The only difference between this rejection and the rejection in the prior action appears to be the addition of Stuart et al. The disclosure of this reference which has been relied on by the Examiner appears at page 7 and reads as follows:

Stuart et al. discloses an emollient gel useful as an ingredient in cosmetics. The emollient gel is composed of 40-90% of an oil or blend of oils and 2-6% of a thickening wax, or a blend of thickening wax. Oils disclosed include jojoba oil and borage oil. See Claims.

To begin with, it must be noted, as specifically appears in the Abstract, that Stuart et al. discloses:

An emollient gel useful as an ingredient in inks, paint, lubricants, grease and cosmetics as a replacement for petroleum in such applications.

Applicants' claimed composition is not an ink, paint, lubricant, grease or cosmetic. The Stuart et al. reference therefore relates to non-analogous art. As such, one skilled in the art would not be led from the disclosure of this reference to select the combination of ingredients which form applicants' therapeutic composition.

Also, to the extent that the Examiner has relied on Stuart et al.'s disclosure of jojoba oil and borage oil, such reliance is misplaced and cannot support the rejection since the disclosures of the four cited references still fail to suggest applicants' therapeutic composition.

With respect to the Declaration of Frank Marchese, the Examiner states, in numbered paragraph 2 of the Action, that "it refer(s) only to the system described in the above-referenced application and not the individual claims of the application. It is respectfully submitted that the Examiner has missed the purpose, and misinterpreted the crux of the affidavit. The Marchese Declaration when correctly viewed under the doctrine enunciated by In re Stempel, 113 U.S.P.Q. 77 (CCPA 1957), mandates removal of Stuart et al. as a reference. In In re Stempel, *supra*, the court rejected a contention similar to what has been raised by the Examiner in the present application by stating (*Id* at 79):

We are of the opinion that the examiner is in error in holding the affidavit insufficient to overcome these references, because it is not ordinarily the function of an affidavit under old Rule 75 to show the invention as *claimed* has been reduced to practice prior to the date of the reference which it aims to overcome. *It is sufficient if it shows that as much of the claimed invention as is taught in the reference has been reduced to practice by the appellant prior to the date of the reference.*
[Emphasis in original.]

The Stuart et al. reference is based of an application filed May 23, 2003, as a continuation of application no. 10/126,414 filed April 19, 2002, now abandoned, which is a continuation-in-part application no. 09/994,416 filed November 27, 2001, also now abandoned. The earliest date alleged by the Stuart et al. reference November 27, 2001, which is subsequent to the date alleged in the Marchese Declaration. Thus, insofar as this reference discloses the use of jojoba and borage oil, albeit for non-analogous composition, it is predicated by the Marchese Declaration and hence it can not be used as a reference against the claims in issue.

As stated in the earlier amendment filed November 18, 2003, Gehling et al., too, cannot be applied as a reference against the claims in issue for the same legal reasons stated above in connection with the Stuart et al. reference.

In sum, the claims in issue, i.e., claims 1-6, 13-18 and 25-31 are patentable over the cited references since

1. Neither Gehling et al. nor Stuart et al. can be applied as references against these claims
2. Stuart et al. is directed to non-analogous art
3. Even if the disclosure of all the references could be legally combined, they still fail to suggest the unique composition defined by the present claims

In addition, claims 7-12 and 19-24 are also patentable since they depend on claims which are now believed to be allowable.

Entry of this Response is requested for the purpose of an appeal.

Respectfully submitted,



James W. Badie, Reg. No. 20,968
Attorney for Applicants
Stoll, Miskin & Badie
The Empire State Building
350 Fifth Avenue, Suite 4710
New York, New York 10118
Telephone: (212) 244-5632



PTO/SB92 (08-00)

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